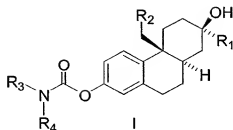


CLAIMS

1. A compound of Formula I



5

a prodrug of said compound, or a pharmaceutically acceptable salt of said compound or prodrug;

wherein R₁ is a) -(C₁-C₆)alkyl optionally substituted with -CF₃, b) -C≡C-CH₃, c) -C≡C-Cl, d) -C≡C-CF₃, e) -CH₂O-(C₁-C₄)alkyl optionally substituted with -CF₃ or f) -CF₃;

10

R₂ is a) -(C₁-C₅)alkyl, b) -(C₂-C₆)alkenyl or c) -phenyl optionally substituted with one of the following: -OH, -NR₉-C(O)-(C₂-C₄)alkyl, -CN, -Z-het, -O-(C₁-C₃)alkyl-C(O)-NR₉R₁₀, -NR₉-Z-C(O)-NR₉R₁₀, -Z-NR₉-SO₂-R₁₀, -NR₉-SO₂-het, -O-C(O)-(C₁-C₄)alkyl or -O-SO₂-(C₁-C₄)alkyl;

15

Z for each occurrence is independently -(C₀-C₄)alkyl;

R₃ is a) -hydrogen, b) -(C₁-C₆)alkyl optionally substituted with one to three halo, c) -(C₂-C₆)alkenyl or d) -(C₂-C₆)alkynyl optionally substituted with one to three halo; R₄ is a) -hydrogen, b) -(C₂-C₆)alkyl-NR₅R₆ or c) -(C₀-C₅)alkyl-het; or R₃ and R₄ are taken together with N to form het;

20

R₅ and R₆ are each independently a) hydrogen or b) -(C₁-C₃)alkyl;

het is an optionally substituted 5-, 6- or 7-membered saturated, partially saturated or unsaturated heterocyclic ring containing from 1 to 3 heteroatoms selected from the group consisting of nitrogen, oxygen and sulfur; and including any bicyclic group in which any of the above heterocyclic rings is fused to a benzene ring or another heterocyclic ring; and optionally substituted with one to four R₇; provided that het is other than pyridinyl, imidazolyl or tetrazolyl;

25

R₇ is a) -(C₁-C₅)alkyl optionally substituted with one to three R₈, b) -Z-NR₉R₁₀ or c) -Z-C(O)-NR₉R₁₀;

R_8 for each occurrence is independently a) halo, b) $-OH$, c) oxo or d) $-O(C_1-C_6)alkyl$;

R_9 and R_{10} for each occurrence are independently a) $-H$ or b) $-(C_1-C_3)alkyl$;
or R_9 and R_{10} are taken together with N to form het;

5 provided that:

1) when R_1 is $-C\equiv C-CH_3$, R_2 is phenyl and R_3 is hydrogen, then R_4 is other than $-(CH_2)_2-N(CH_3)_2$, $-(CH_2)_3-N(CH_3)_2$, $-(CH_2)_2$ -pyrrolidinyl optionally substituted with methyl, $-(CH_2)_2$ -pyrrolidinyl or $-(CH_2)_2$ -morpholinyl;

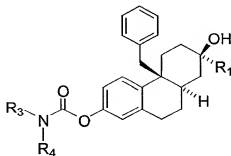
2) when R_1 is $-C\equiv C-CH_3$, R_2 is $-CH_2-CH=CH_2$ and R_3 is hydrogen, then R_4 is
10 other than $-(CH_2)_2$ -pyrrolidinyl;

3) when R_1 is $-C\equiv C-CH_3$, R_2 is propyl and R_3 is hydrogen, then R_4 is other than $-(CH_2)_2-N(CH_3)_2$ or $-(CH_2)_2$ -pyrrolidinyl;

4) when R_1 is $-C\equiv C-CH_3$, R_2 is butyl and R_3 is hydrogen, then R_4 is other than $-(CH_2)_2-N(CH_3)_2$, $-(CH_2)_2$ -pyrrolidinyl or $-(CH_2)_2$ -morpholinyl; and

15 5) when R_1 is $-C\equiv C-CH_3$, R_2 is pentyl and R_3 is hydrogen, then R_4 is other than $-(CH_2)_2$ -morpholinyl or $-(CH_2)_2$ -pyrrolidinyl.

2. A compound of claim 1 of Formula II



II

20 a prodrug of said compound or a pharmaceutically acceptable salt of said compound or prodrug;

wherein R_1 is a) $-(C_1-C_6)alkyl$ optionally substituted with $-CF_3$, b) $-C\equiv C-CH_3$, c) $-CF_3$ or d) $-CH_2O(C_2-C_4)alkyl$.

3. A compound of claim 2 wherein R_1 is a) $-CH_2CH_2CH_3$, b) $-C\equiv C-CH_3$ or c) $-CF_3$.
25

4. A compound of claim 3 wherein R_3 is a) hydrogen, b) methyl, c) ethyl, d) propyl or e) isopropyl;

R_4 is $-(C_2-C_3)alkyl-NR_5R_6$;

R₅ and R₆ are each independently a) methyl, b) ethyl, c) propyl or d) isopropyl.

5. A compound of claim 4
wherein R₃ is a) methyl, b) ethyl, c) propyl or d) isopropyl;

5 R₄ is -(C₂-C₃)alkyl-NR₅R₆;
R₅ and R₆ are each independently a) methyl, b) ethyl, c) propyl or d) isopropyl.

6. A compound of claim 5
wherein R₃ is a) methyl or b) ethyl;

10 R₄ is -(C₂-C₃)alkyl-NR₅R₆;
R₅ and R₆ are each methyl.

7. A compound of claim 3
wherein R₃ is a) hydrogen, b) methyl or c) ethyl;
R₄ is -(C₀-C₄)alkyl-het;

15 het is a) morpholinyl, b) pyrrolidinyl, c) piperidinyl, d) piperazinyl, e) hexahydro-azepinyl, f) azabicyclo[2.2.2]oct-3-yl, g) azabicyclo[3.2.1]oct-3-yl, h) 3,6-diazabicyclo[3.1.1]heptyl or i) 2,5-diazabicyclo[2.2.1]heptyl;
the above het groups are optionally substituted with one to four R₇;
R₇ is a) methyl, b) ethyl or c) -NR₉R₁₀;

20 R₉ and R₁₀ are each independently methyl or ethyl.

8. A compound of claim 7
wherein R₃ is a) hydrogen, b) methyl or c) ethyl;
R₄ is -(C₀-C₃)alkyl-het;

25 e) azabicyclo[3.2.1]oct-3-yl;
the above het groups are optionally substituted with one or two R₇;
wherein R₇ is a) methyl or b) ethyl.

9. A compound of claim 8
wherein R₃ is a) methyl or b) ethyl;

30 R₄ is -(C₀-C₃)alkyl-het;
het is a) pyrrolidinyl, b) piperidinyl, c) hexahydro-azepinyl, or d) azabicyclo[3.2.1]oct-3-yl;
the above het groups are optionally substituted with one R₇;
wherein R₇ is a) methyl or b) ethyl.

10. A compound of claim 3 wherein R_3 and R_4 are taken together with N to form het;
wherein het is a) piperazinyl, b) pyrrolidinyl, c) piperidinyl, d) 2,5-diazabicyclo[2.2.1]heptyl, e) azetidiny, f) 1,4-diazabicyclo[3.2.2]nonanyl, g) 3,6-diazabicyclo[3.2.2]nonanyl, h) octahydro-pyrido[1,2-a]pyrazinyl or i) hexahydro-1,4-diazepinyl;
- the above het groups are optionally substituted with one or two R_7 ;
- R_7 is a) $-(C_1-C_2)$ alkyl optionally substituted with one or two R_8 , b) $-(C_0-C_2)$ alkyl- NR_9R_{10} or c) $-Z-C(O)-NR_9R_{10}$;
- 10 R_8 is -OH;
- R_9 and R_{10} are each independently a) hydrogen b) methyl or c) ethyl;
or R_9 and R_{10} are taken together with N to form a) pyrrolidinyl or b) piperidinyl.
11. A compound of claim 10 wherein R_3 and R_4 are taken together with N to form het;
- 15 wherein het is a) pyrrolidinyl, b) piperidinyl or c) azetidinyl;
the above het groups are optionally substituted with one R_7 ;
- R_7 is $-CH_2-NR_9R_{10}$;
- R_9 and R_{10} are each independently a) methyl or b) ethyl;
or R_9 and R_{10} are taken together with N to form a) pyrrolidinyl or b)
- 20 piperidinyl.
12. A compound of claim 1
wherein R_1 is a) $-CH_2CH_2CH_3$, b) $-C\equiv C-CH_3$ or c) $-CF_3$;
- R_2 is a) $-(C_1-C_5)$ alkyl or b) $-(C_2-C_5)$ alkenyl;
- R_3 is a) hydrogen, b) methyl, c) ethyl, d) propyl or e) isopropyl;
- 25 R_4 is $-(C_2-C_3)$ alkyl- NR_5R_6 ;
- R_5 and R_6 are each independently a) methyl, b) ethyl, c) propyl or d) isopropyl.
13. A compound of claim 12
wherein R_2 is a) methyl, b) ethyl, c) propyl, d) ethenyl, e) propenyl or f) butenyl;
- 30 R_3 is a) hydrogen, b) methyl or c) ethyl,
- R_5 and R_6 are each independently a) methyl or b) ethyl.
14. A compound of claim 1
wherein R_1 is a) $-CH_2CH_2CH_3$, b) $-C\equiv C-CH_3$ or c) $-CF_3$;
- R_2 is a) $-(C_1-C_5)$ alkyl or b) $-(C_2-C_5)$ alkenyl;

R₃ is a) hydrogen, b) methyl, c) ethyl, d) propyl or e) isopropyl;

R₄ is -(C₀-C₄)alkyl-het;

het is a) morpholinyl, b) pyrrolidinyl, c) piperidinyl or d) piperazinyl;

the above het groups are optionally substituted with one or two R₇;

5 R₇ is a) methyl, b) ethyl or c) -NR₉R₁₀;

R₉ and R₁₀ are each independently methyl or ethyl.

15. A compound of claim 14

wherein R₂ is a) methyl, b) ethyl, c) propyl, d) ethenyl, e) propenyl or f) butenyl;

R₃ is a) hydrogen, b) methyl or c) ethyl;

10 R₄ is -(C₂-C₃)alkyl-het;

het is a) morpholinyl or b) pyrrolidinyl;

the above het groups are optionally substituted with one or two R₇;

wherein R₇ is a) methyl or b) ethyl.

16. A compound of claim 1

15 wherein R₁ is a) -CH₂CH₂CH₃, b) -C≡C-CH₃ or c) -CF₃;

R₂ is a) -(C₁-C₆)alkyl or b) -(C₂-C₆)alkenyl;

R₃ and R₄ are taken together with N to form het;

het is a) piperazinyl, b) pyrrolidinyl or c) piperidinyl;

the above het groups are optionally substituted with one or two R₇;

20 R₇ is a) -(C₁-C₂)alkyl optionally substituted with one or two R₈, b) -(C₀-

C₂)alkyl-NR₉R₁₀ or c) -Z-C(O)-NR₉R₁₀;

R₈ is -OH;

R₉ and R₁₀ are each independently a) hydrogen b) methyl or c) ethyl;

or R₉ and R₁₀ are taken together with N to form a) pyrrolidinyl or b)

25 piperidinyl.

17. A compound of claim 16

wherein R₂ is a) methyl, b) ethyl, c) propyl, d) ethenyl, e) propenyl or f) butenyl;

het is a) pyrrolidinyl or b) piperidinyl;

the above het groups are optionally substituted with one R₇;

30 R₇ is -CH₂-NR₉R₁₀;

R₉ and R₁₀ are each independently a) methyl or b) ethyl;

or R₉ and R₁₀ are taken together with N to form a) pyrrolidinyl or b)

piperidinyl.

18. A compound of claim 1 wherein in Formula I -CH₂-R₂ is ethenyl or ethynyl.

19. A compound of claim 4 selected from the group consisting of:
carbamic acid, [2-(dimethylamino)ethyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester;
carbamic acid, [3-(dimethylamino)propyl]-, (4bS,7R,8aR)-
- 5 4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester; and
carbamic acid, [3-(diethylamino)propyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester.
20. A compound of claim 6 selected from the group consisting of:
carbamic acid, [2-(dimethylamino)ethyl]methyl-, (4bS,7R,8aR)-
- 10 4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester;
carbamic acid, [2-(dimethylamino)ethyl]methyl-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-propyl-2-phenanthrenyl ester;
- 15 carbamic acid, [3-(dimethylamino)propyl]ethyl-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester; and
carbamic acid, [2-(dimethylamino)ethyl]ethyl-, (4bS,7R,8aR)-
- 20 4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester.
21. A compound of claim 8 selected from the group consisting of:
carbamic acid, [2-(1-pyrrolidinyl)ethyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester;
- 25 carbamic acid, [2-(1-piperidinyl)ethyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester;
carbamic acid, [3-(hexahydro-1H-azepin-1-yl)propyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester;
- 30 carbamic acid, [3-(1-pyrrolidinyl)propyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester;
carbamic acid, [2-(1-pyrrolidinyl)ethyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-propyl-2-phenanthrenyl ester;

- carbamic acid, [2-(1-piperidinyl)ethyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-propyl-2-phenanthrenyl ester;
- carbamic acid, (1-ethyl-3-piperidinyl)-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl;
- 5 carbamic acid, [(3-exo)-8-methyl-8-azabicyclo[3.2.1]oct-3-yl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester;
- carbamic acid, [(1-ethyl-2-pyrrolidinyl)methyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester;
- 10 carbamic acid, [3-(hexahydro-1H-azepin-1-yl)propyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-propyl-2-phenanthrenyl ester;
- carbamic acid, [[[2R]-1-ethyl-2-pyrrolidinyl]methyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester;
- 15 carbamic acid, [3-(1-piperidinyl)propyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester;
- carbamic acid, [3-(1-pyrrolidinyl)propyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-propyl-2-phenanthrenyl ester;
- 20 carbamic acid, [[[2S]-1-ethyl-2-pyrrolidinyl]methyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-propyl-2-phenanthrenyl ester;
- carbamic acid, [[[2R]-1-ethyl-2-pyrrolidinyl]methyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-propyl-2-phenanthrenyl ester;
- 25 carbamic acid, [2-(4-morpholinyl)ethyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester; and
- 30 carbamic acid, [3-(4-morpholinyl)propyl]-, (4bS,7R,8aR)-4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-phenanthrenyl ester.
22. A compound of claim 11 selected from the group consisting of:

1-pyrrolidinecarboxylic acid, 2-(1-pyrrolidinylmethyl)-, (4bS,7R,8aR)-
4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-
phenanthrenyl ester;

- 5 1-piperidinecarboxylic acid, 2-(1-piperidinylmethyl)-, (4bS,7R,8aR)-
4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-
phenanthrenyl ester;

1-piperidinecarboxylic acid, 2-[(dimethylamino)methyl]-, (4bS,7R,8aR)-
4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-
phenanthrenyl ester;

- 10 1-piperidinecarboxylic acid, 2-[(diethylamino)methyl]-, (4bS,7R,8aR)-
4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-
phenanthrenyl ester; and

1-azetidinecarboxylic acid, 3-(1-piperidinyl)-, (4bS,7R,8aR)-
4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-
phenanthrenyl ester.

- 15 23. Carbamic acid, (2,2,6,6-tetramethyl-4-piperidinyl)-, (4bS,7R,8aR)-
4b,5,6,7,8,8a,9,10-octahydro-7-hydroxy-4b-(phenylmethyl)-7-(trifluoromethyl)-2-
phenanthrenyl ester, a compound of claim 7.

24. A compound of claim 13 selected from the group consisting of:
20 carbamic acid, (3-dimethylaminopropyl)methyl-, (4bS, 7R, 8aR)-
4b,5,6,7,8,8a,9,10-octahydro-4b-ethyl-7-hydroxy-7-prop-1-ynyl-phenanthren-2-yl
ester;

carbamic acid, (2-dimethylaminoethyl)methyl-, (4bS, 7R, 8aR)-
4b,5,6,7,8,8a,9,10-octahydro-4b-ethyl-7-hydroxy-7-prop-1-ynyl-phenanthren-2-yl
25 ester;

carbamic acid, (2-dimethylaminoethyl)ethyl-, (4bS, 7R, 8aR)-
4b,5,6,7,8,8a,9,10-octahydro-4b-ethyl-7-hydroxy-7-prop-1-ynyl-phenanthren-2-yl
ester; and

- 30 carbamic acid, (2-dimethylaminoethyl)-, (4bS, 7R, 8aR)-4b,5,6,7,8,8a,9,10-
octahydro-4b-ethyl-7-hydroxy-7-prop-1-ynyl-phenanthren-2-yl ester.

25. A compound of claim 15 selected from the group consisting of:
carbamic acid, (3-morpholin-4-yl-propyl)-, (4bS, 7R, 8aR)-
4b,5,6,7,8,8a,9,10-octahydro-4b-ethyl-7-hydroxy-7-prop-1-ynyl-phenanthren-2-yl
ester;

carbamic acid, (2-pyrrolidin-1-yl-ethyl)-, (4bS, 7R, 8aR)-4b,5,6,7,8,8a,9,10-octahydro-4b-ethyl-7-hydroxy-7-prop-1-ynyl-phenanthren-2-yl ester; and

carbamic acid, (2-morpholin-4-yl-ethyl)-, (4bS, 7R, 8aR)-4b,5,6,7,8,8a,9,10-octahydro-4b-ethyl-7-hydroxy-7-prop-1-ynyl-phenanthren-2-yl ester.

- 5 26. 2-Pyrrolidin-1-ylmethylpyrrolidine-1-carboxylic acid, (4bS, 7R, 8aR)-4b,5,6,7,8,8a,9,10-octahydro-4b-ethyl-7-hydroxy-7-prop-1-ynylphenanthren-2-yl ester, a compound of claim 17.
27. A method for the treatment of a glucocorticoid receptor-mediated disease or condition in a mammal, which comprises administering to the mammal a
- 10 therapeutically effective amount of a compound of claim 1, a prodrug thereof, or a pharmaceutically acceptable salt of said compound or prodrug.
28. The method of claim 27 wherein the glucocorticoid receptor-mediated disease or condition is selected from the group consisting of obesity, diabetes, depression, anxiety and neurodegeneration.
- 15 29. The method of claim 28 wherein the condition is obesity.
30. The method of claim 29 which further comprises administering a β_3 agonist, a tyromimetic agent, an eating behavior modifying agent or a NPY antagonist.
31. The method of claim 30 wherein the eating behavior modifying agent is orlistat or sibutramine.
- 20 32. The method of claim 28 wherein the disease is diabetes.
33. The method of claim 32 which further comprises administering an aldose reductase inhibitor, a glycogen phosphorylase inhibitor, a sorbitol dehydrogenase inhibitor, insulin, a sulfonyleurea, glipizide, glyburide, or chlorpropamide.
34. The method of claim 27 wherein the glucocorticoid receptor-mediated
- 25 disease is an inflammatory disease.
35. A pharmaceutical composition comprising a therapeutically effective amount of a compound of claim 1, a prodrug of said compound or a pharmaceutically acceptable salt of said compound or prodrug; and a pharmaceutically acceptable carrier, vehicle or diluent.
- 30 36. A pharmaceutical combination composition comprising: a therapeutically effective amount of a composition comprising:
- a first compound, said first compound being a compound of claim 1, a prodrug of said compound or a pharmaceutically acceptable salt of said compound, or prodrug;

a second compound, said second compound being a β_3 agonist, a thyromimetic agent, an eating behavior modifying agent or a NPY antagonist; and a pharmaceutical carrier, vehicle or diluent.

37. A kit comprising:

5 a) a first compound, said first compound being a compound of claim 1, a prodrug of said compound or a pharmaceutically acceptable salt of said compound, or prodrug and a pharmaceutically acceptable carrier, vehicle or diluent in a first unit dosage form;

10 b) a second compound, said second compound being a β_3 agonist, a thyromimetic agent, an eating behavior modifying agent or a NPY antagonist; and a pharmaceutically acceptable carrier, vehicle or diluent in a second unit dosage form; and

c) a container for containing said first and second dosage forms; wherein the amounts of said first and second compounds result in a therapeutic effect.

15 38. A method for inducing weight loss in a mammal which comprises administering to the mammal a therapeutically effective amount of a compound of claim 1, a prodrug of said compound or a pharmaceutically acceptable salt of said compound or prodrug.

20 39. A pharmaceutical combination composition comprising: a therapeutically effective amount of a composition comprising:

a first compound, said first compound being a compound of claim 1, a prodrug of said compound or a pharmaceutically acceptable salt of said compound or prodrug;

25 a second compound, said second compound being an aldose reductase inhibitor, a glycogen phosphorylase inhibitor, a sorbitol dehydrogenase inhibitor, insulin, a sulfonylurea, glipizide, glyburide, or chlorpropamide; and a pharmaceutical carrier, vehicle or diluent.

30 40. A method for the treatment of an inflammatory disease in a mammal which comprises administering to said mammal a therapeutically effective amount of a compound of claim 1, a prodrug of said compound or a pharmaceutically acceptable salt of said compound or prodrug.

41. The method of claim 40 wherein the inflammatory disease is selected from the group consisting of arthritis, asthma, rhinitis and immunomodulation.